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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,697

08/14/2002

Ajay Kumar Luthra

16230-8677

8586

21888

7590

08/31/2006

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 08/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,697	<b>Applicant(s)</b> LUTHRA ET AL.	
	<b>Examiner</b> Micah-Paul Young	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-66 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                            | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

### **DETAILED ACTION**

**Acknowledgment of Papers Received:** Remarks dated 6/5/06.

#### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 39,41,43-45,47-49,51-54,56-63 and 66 rejected under 35 U.S.C. 102(b) as being anticipated by Olstein (USPN 5,142,010 hereafter '010). The claims are drawn to a polymeric biguanide and a method of making the same.

3. The '010 patent teaches a polymeric biguanide formulation where one of the nitrogen atoms is bond by an amine linkage (col. 2, lin. 15-65). The polymer formed is infection resistant and is useful in bulk polymers and copolymers (col. 3, lin. 49-65). The polymeric material is incorporated into various forms useful in or on the human body and as a coating, or an implantable medical device (col. 4, lin. 54-65; col. 13, lin. 21-36). The reaction sites binding to the polymer include isocyanate (col. 2, lin. 56-60). The polymers are subsequently blended with other polymers such as acrylic acid derivatives and methacrylate derivatives (col. 9, lin. 50-65). The formation of the polymer requires a polymerization process (col. 10, lin. 51-68). The polymers are combined with polymers useful for ocular lenses such as silicones (col. 12, lin.20-25). Though the reference discloses the combination of polymeric biguanides with silicon reactive polymers, and other polymers useful for intra-ocular lenses, it is the position of the

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Examiner that such claim limitations are merely a future intended use. Where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation. See also *Rowe v. Dror*, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

4. Regarding the coupling agent it is the position of the Examiner that such limitations do not impart patentability on the claims barring a showing of criticality to the couple agent. The products made by the method are identical and function in the same way. Applicant is invited to provide evidence of patentable distinction between the products made by the method of the prior art and those of the instant claims. Until such evidence can be provided the claims remain anticipated.

5. For these reasons the claims are anticipated by the '010 reference.

6. Claims 39,41,46,50 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Buckley et al (GB 1,531,717 hereafter '717). The claims are drawn to a polymeric biguanide and a method of making the same.

7. The '717 patent teaches a polymeric biguanide and method of making the same comprising isolating a substantially free base of a biguanide and bonding with a polymer (page 3, lin. 1-10). The polymer bound to the nitrogen of the biguanide can be an aliphatic-aromatic radical having two or more amide or urea linkages (page 1, lin. 25-30). The formulation can take various forms including solid bulk, powder or liquid form. These forms represent a medical device form. For these reasons the '717 patent anticipates the claims.

***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 40,42,48, 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures Olstein (USPN 5,142,010 hereafter '010) and Solomon et al (USPN 5,451,424 hereafter '424). The claims are drawn to a polymeric biguanide and a method of making the same.

11. As discussed above the '010 patent discloses a biguanide polymeric material yet is silent to the specific biguanide used. The inclusion of a specific biguanide is well within the level of skill in the art as seen in the '424 patent.

12. The '424 patent discloses a biguanide polymer comprising chlorhexidine (abstract). The biguanide is bound to polyurethane and used for medical tubing (example 1). Polyurethane is one

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of the many polymers used in grafting the biguanides of the '010 patent, therefore a skilled artisan would be motivated to include the biguanides of the '424 into the preparation of the '010.

13. Regarding the coupling agent it is the position of the Examiner that such limitations do not impart patentability on the claims barring a showing of criticality to the couple agent. The products made by the method are identical and function in the same way. Applicant is invited to provide evidence of patentable distinction between the products made by the method of the prior art and those of the instant claims. The Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

14. With these things in mind it would have been obvious to incorporate the biguanides of the '424 patent into the preparation of the '010 in order to fight a wide range of bacterial infections. One of ordinary skill in the art would have been motivated to combine the teachings and references with an expected result of an infection resistant polymer.

### ***Response to Arguments***

15. Applicant's arguments with respect to claims 39-66 have been considered but are moot in view of the new ground(s) of rejection.


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*Correspondence*

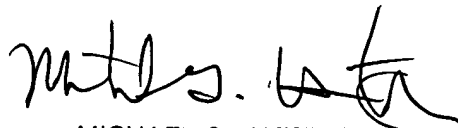
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MP Young

Micah-Paul Young  
Examiner  
Art Unit 1618

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER